



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0008]

Patient Engagement Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) announces a forthcoming public advisory committee meeting of the Center for Devices and Radiological Health (CDRH) Patient Engagement Advisory Committee (the Committee). The general function of the committee is to provide advice to the Commissioner of Food and Drugs, or designee, on complex scientific issues relating to medical devices, the regulation of devices, and their use by patients. The meeting will be open to the public.

DATES: The meeting will take place virtually on September 6, 2023, from 10 a.m. to 5:20 p.m. Eastern Time.

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at:

<https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

Information on how to access the webcast will be made available no later than 2 business days prior to the meeting at <https://www.fda.gov/advisory-committees/committees-and-meeting-materials/patient-engagement-advisory-committee>. Select the link for the 2023 Meeting Materials.

FOR FURTHER INFORMATION CONTACT: Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm.

5407, Silver Spring, MD 20993-0002, letise.williams@fda.hhs.gov, 301-796-8398, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the *Federal Register* about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/advisory-committees> and scroll down to the appropriate advisory committee meeting link or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On September 6, 2023, the Committee will discuss and make recommendations on the topic of "Advancing Health Equity in Medical Devices." FDA CDRH is committed to working toward ensuring that all patients have access to high-quality, safe, and effective medical devices. This includes ensuring devices are designed to be safe and effective when used by various populations, are evaluated in the diverse populations for which they are intended, and that patients and consumers have the information they need to make decisions about their health, care and quality of life. Technology, including digital health technology, may help bridge gaps in health equity by extending access and bringing healthcare to patients at home, at work, and in their communities. The recommendations provided by the committee will address considerations for FDA and industry on these topics. The Committee will consider ways to advance access to devices that allow for care outside a hospital or clinical care setting--for example, in the home setting. The Committee will also discuss considerations for improving reach and comprehension of FDA's patient and caregiver communications across diverse demographic groups. Additionally, the Committee will discuss patient-focused considerations for when a device should be evaluated in diverse populations to support marketing authorization.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background materials and the link to the online teleconference meeting room will be available at <https://www.fda.gov/advisory-committees/committees-and-meeting-materials/patient-engagement-advisory-committee>. Select the link for the 2023 Meeting Materials. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person (see FOR FURTHER INFORMATION CONTACT) on or before August 10, 2023. Oral presentations from the public will be scheduled on September 6, 2023, between approximately 2:15 p.m. to 3:15 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person on or before August 2, 2023. The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 3, 2023.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at Annmarie.Williams@fda.hhs.gov, or 240-507-6496 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-10609 Filed: 5/17/2023 8:45 am; Publication Date: 5/18/2023]